COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 23/02/2001
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NOT FOR PUBLICATION

COMMISSION DECISION

of 23/02/2001

granting the marketing authorization for the medicinal

product for human use,

"Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase"

ONLY THE GERMAN TEXT IS AUTHENTIC.

(Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], and in particular Article 10(1) and (2) thereof,

Having regard to the application submitted by Boehringer Ingelheim International GmbH, on 24 September 1999, under Article 4(1) of Regulation (EEC) No 2309/93, concerning the medicinal product, "Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase",

Having regard to the opinion of 18 October 2000 of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products,

Whereas:

(1) The medicinal product, "Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase", complies with the requirements of Council Directives 65/65/EEC[2], 75/318/EEC[3] and 75/319/EEC[4], as last amended by Directive 93/39/EEC[5];

(2) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ No 22, 9.2.1965, p. 369/65.
[3] OJ No L 147, 9.6.1975, p. 1.
[4] OJ No L 147, 9.6.1975, p. 13.
[5] OJ No L 214, 24.8.1993, p. 22.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorization referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted in respect of the medicinal product, "Tenecteplase Boehringer Ingelheim Pharma KG - tenecteplase" whose characteristics are summarized in Annex I hereto. This medicinal product shall be entered in the Community Register of Medicinal Products under the numbers:

EU/1/00/168/001	Tenecteplase Boehringer Ingelheim Pharma KG - 6,000 units (30 mg) - Powder and solvent for solution for injection - Intravenous use - 1 vial + 1 pre-filled syringe
EU/1/00/168/002	Tenecteplase Boehringer Ingelheim Pharma KG - 8,000 units (40 mg) - Powder and solvent for solution for injection - Intravenous use - 1 vial + 1 pre-filled syringe
EU/1/00/168/003	Tenecteplase Boehringer Ingelheim Pharma KG - 10,000 units (50 mg) - Powder and solvent for solution for injection - Intravenous use - 1 vial + 1 pre-filled syringe

Article 2

The marketing authorization concerning the medicinal product referred to in Article 1 shall be subject to compliance with all the conditions, particularly those relating to manufacture and/or importation, control and issue referred to in Annex II.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision. It shall be renewable under the conditions laid down in Article 13(1) of Regulation (EEC) No 2309/93.

Article 5

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 23/02/2001

For the Commission
Erkki LIIKANEN
Member of the Commision